MAY 2 1 2014

K133738

510(k) Summary

21 CFR 807.87(h)

As required by 21 CFR 807.92(a)

(1) Date Prepared: December 6, 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The NovoFine® Plus needle meets all applicable product and quality standards for hypodermic single lumen needle products.

Submitter's Name and Address:

Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, New Jersey 08536

Contact Person:
Rick Spring
Associate Director, Regulatory Affairs
Tel: 609-987-5046
Fax: 609-987-3916

(2) Name of Device:

Proprietary Name:	NovoFine® **Plus** 32G x 4 mm
Common or usual name:	Sterile disposable hypodermic needle
Classification Name:	Hypodermic single lumen needle (21 CFR 880.5570)
Class:	Class II
Product Code:	FMI

(3) Substantial Equivalence:

NovoFine® Plus is a disposable needle which is substantially equivalent to Novo Nordisk's NovoFine® 32G Tip x 6 mm needle, cleared under 510(k) K090111, and NovoTwist® 32G Tip x 5 mm needle, cleared under 510(k) K093109, and to Becton Dickinson's BD Pen Needle 32G x 4 mm, cleared under 510(k) K123300.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as supplied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statement related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent laws or their application by the court.

(4) Device Description:

NovoFine® Plus needles are single use, sterile needles to be used in conjunction with pen injector devices. Prior to giving an injection, the protective tab is removed from the outer needle cap of the single-use disposable needle. With the disposable needle remaining in the outer needle cap, it is then carefully screwed onto the injection delivery device until tight and then the needle outer and inner caps are removed. Use the needles as described in the instructions for use that comes with the pen-injector device and as instructed by the healthcare professional. After the injection, the needle is removed from the skin. The needle is detached from the injection device and disposed of in accordance with national/local regulations. For each subsequent injection, another disposable needle must be used.

(5) Intended Use:

NovoFine® Plus 32G is intended for use with pen injector devices for the subcutaneous injection of drugs, including insulin, GLP-1 analogs, and somatropin.

(6) Technological Characteristics:

The NovoFine® Plus needle is considered substantially equivalent to the NovoFine® 32G Tip x 6 mm disposable needle, NovoTwist® 32G Tip x 5 mm, and to the BD Pen Needle 32G x 4 mm in intended use, technology, principles of operation, materials and performance. Differences between the devices do not raise any significant issues of safety and effectiveness. For a detailed side by side comparison to the predicate needles cleared by the Agency, please see the table: Comparison to a legally marketed device.

As required by 21 CFR 807.92(b)

(1) Non-Clinical Tests Performed:

The NovoFine® Plus needle will be manufactured in accordance with current Good Manufacturing Practices for Medical Devices. Biocompatibility and performance tests have been performed and the results are in compliance with existing domestic and international standards.

The NovoFine® Plus 32G 4 mm needles have been subjected to non-clinical tests throughout the development by Novo Nordisk R&D, and these tests comply with *ISO 11608-2:2012 Pen injectors for medical use - Part 2: Needles - Requirements and test methods.*

The needle samples tested are manufactured, sterilized, packaged, and labelled on validated equipment and QA-released in accordance with cGMP for Medical Devices as per *ISO 13485:2012 Medical devices – Quality Management systems Requirements for regulatory purposes.*

The NovoFine® Plus 32G 4 mm needles are subjected to a final design verification test. The design verification of the NovoFine® Plus 32G 4 mm needles has been conducted as per *ISO 11607-1:2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.* In summary, the final design verification test supports that NovoFine® Plus 32G 4 mm needles meet the specified requirements and that the needles can be safely used according to the Instructions for Use.

Shelf life testing has been performed on the final released NovoFine® Plus 32G 4 mm needles in accordance with *ASTM F1980 – 07: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*

The biocompatibility tests for NovoFine Plus® 32G 4mm needles were conducted in accordance with *ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system.*

(2) Clinical Tests Performed:

No clinical tests are required.

(3) Conclusion drawn from the non-clinical and clinical tests:

Based on the design equivalency and the functional testing, Novo Nordisk has determined that the NovoFine® Plus is substantially equivalent to NovoFine® 32G Tip 6 mm, K090111, NovoTwist® 32G Tip x 5 mm, K093109, and to the Becton Dickinson (BD) Pen Needle 32G x 4 mm, K123300, which are currently marketed in the United States. Differences between the devices do not raise any significant issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

Novo Nordisk Incorporated
Mr. Rick Spring
Associate Director, Regulatory Affairs
Post Office Box 846
Plainsboro, NJ 08536

Re: K133738

Trade/Device Name: NovoFine® Plus 32G x 4 mm (1/6") Disposable Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 25, 2014
Received: April 28, 2014

Dear Mr. Spring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133738

Device Name
NovoFine® Plus 32G x 4 mm (1/6") Disposable Needle

Indications for Use *(Describe)*
NovoFine® Plus needles are intended for use with pen injector devices for the subcutaneous injection of drugs, including insulin, GLP-1 analogs, and somatropin.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by
Richard C. Chapman
Date: 2014.05.21
14:00:36 -04'00'